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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY-DOCKET NO.	CONFIRMATION NO.
10/517,323	12/20/2004	Masazumi Nishikawa	263192US0PCT	3573
22850 7590 10/16/2007 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER MERCIER, MELISSA S	
			PART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 10/16/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

## Office Action Summary

Application No.

10/517,323

Applicant(s)

NISHIKAWA ET AL.

Examiner

Melissa S. Mercier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Summary**

Receipt of Applicants remarks and amended claims filed on August 8, 2007 is acknowledged. Claims 18-38 are under prosecution in this application. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising shark liver oil subjected to degumming and deacidification treatment and vacuum distillation so as to remove hydrocarbon components, and then subjected to decolorization and steam distillation using active clay, thereby preparing a composition containing diacylglycerol ether (containing 66.4% diacylglycerol ether, 26.3% triglyceride, and 7.3% squalene) does not reasonably provide enablement for a method of administering at least one diacylglycerol ether represented by the formula in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A review of the

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specification discloses the composition comprises diacylglyceryl ether, triglyceride, and squalene in combination. The specification is not enabled for a method of reducing at least one skin damage with the use of at least one diacylglycerol alone.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Levin (US Patent 5,514,591), in view of Fuisz (US Patent 5,518,730).

Levin discloses the use of shark liver oil to be applied topically as an anti-wrinkle, anticancer, anti-inflammatory, agent (abstract). Applicant's disclosure on page 8 discloses a method for extracting diacylglyceryl ether from shark liver oil. Therefore, it is the examiners position that the use of shark liver oil would inherently possess the ether compound and thus the administration of shark liver oil would yield the same results.

Levin does not disclose the shark liver oil being orally administered.

Fuisz discloses the oral administration of shark liver oil. The composition may further comprise a variety of additives including excipients, lubricants, buffering agents, disintegrating agents, stabilizers, foaming agents, pigments, coloring agents, fillers, bulking agents, sweetening agents, flavoring agents, fragrances, release modifiers, adjuvants, plasticizers, flow accelerators, polyols, granulating agents, diluents, binders, buffers, absorbents, glidants, adhesives, antiadherents, acidulants, softeners, resins,

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demulcents, solvents, surfactants, emulsifiers, elastomers and mixtures thereof (column 10, lines 1-12).

Regarding the form of administration and dosing schedule, Ahmed discloses formulations for oral administration; it is the examiners position that one of ordinary skill in the art would possess the knowledge in order to prepare a variety of formulations including foods, emulsions, syrups, tablets, gums, and liquids. It is further the position of the examiner that one of ordinary skill in this art would have the knowledge for determining optimum dosing schedules of the composition in order to obtain the optimum therapeutic effect of the compound.

Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Levin with the dosage forms taught by Fuisz in order to obtain the convenience of administering a single dose of a medication (column 1, lines 10-12).

### ***Response to Arguments***

Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or

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distinguish from them. Applicant did not address the references other than to state they do not meet the limitation of claim 18 and is silent regarding formation of skin cancer, pigmented spots, freckles, wrinkles, verruca, and erythema. As discussed in the rejection, Levin discloses the use of shark liver oil to be applied topically as an anti-wrinkle, anticancer, anti-inflammatory, agent (abstract). No arguments were submitted regarding the Fuisz reference.

### ***Conclusion***

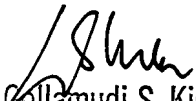
No claims are allowable. Due to the new grounds of rejection presented in this action, this office action is Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

  
Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1800